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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,508	01/26/2001	Susan G. Stuart	BEBIO-111 C1	8243

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09/05/2002

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/769,508

Applicant(s)

STUART ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

The preliminary amendments filed 1/20/02 and 7/18/02 have been entered.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 5 I. Claims 1-12, 19 and 42, drawn to a DNA molecule comprising all or parts of SEQ ID NO:1 or a DNA molecule encoding all or part of SEQ ID NO:2, vector, host cell, and method of producing the encoded protein, classified in class 435, subclass 69.1.
- 10 II. Claims 13-16, 36, 41, 43 and 52-54 drawn to gp75 protein and fragments thereof, kit with protein (no antibody), fused protein and glycoprotein, classified in class 530, subclass 350.
- 15 III. Claims 17-35 and 64, drawn to antibody to gp75 protein and fragments thereof, classified in class 530, subclass 388.22.
- IV. Claims 60 and 36, drawn to anti-idiotypic antibodies to antibodies to gp75 protein and to kit comprising anti-idiotypic antibodies (no gp75 protein), classified in class 530, subclass 387.2.
- V. Claim 36, drawn to kit comprising both gp75 protein and anti-idiotypic antibody, classified in class 530, subclass 350 and 387.2.
- 20 VI. Claims 18 and 59, drawn to a method of treating by administering antibodies to gp75 protein, classified in class 424, subclass 143.1.
- VII. Claims 20-34, 44, 45, 51 and 55-58, drawn to method of testing for the presence of gp75 by using antibody to gp75 protein, classified in class 435, subclass 7.1.
- 25 VIII. Claims 37-40, drawn to vaccine, classified in class 424, subclass 185.1.
- IX. Claims 46-49, drawn to method of treating by administering gp75 protein, classified in class 512, subclass 12.
- X. Claim 50, drawn to method of treating with an anti-idiotypic antibody to a monoclonal antibody to gp75 protein, classified in class 424, subclass 131.1.
- XI. Claims 44, 45, 61 and 63, drawn to method to detect or purify c-erbB-2 ligand by using gp75 protein, classified in class 435, subclass 501.

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XII. Claim 44, 45 and 62, drawn to method to detect anti-gp75 protein antibodies by using gp75 protein, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

5           The DNA molecule of Invention I is related to the protein of Invention II by virtue of encoding the same. For the same reason it is related to the vaccine of Invention VIII. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 19. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein that may or may not be used in the vaccine, they are distinct  
10 inventions because the protein product can be made by another and materially different process, such as by synthesis (claim 43) or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

          The protein and vaccine of Inventions II and VIII, respectively, are related to the  
15 antibody of Invention III by virtue of the protein being the cognate antigen, necessary for the production of the antibody. Also, the antibody of Invention III is related to the anti-idiotypic antibody of Invention IV, since the anti-idiotypic antibody binds the antibody. Although the protein and antibody and the antibody and anti-idiotypic antibody are related due to the necessary steric complementarity of each of the two, they are distinct inventions because the protein can  
20 be used for another and materially different process other than for production of the antibody, such as to assay or purify the natural ligand of the protein (as the protein is itself a receptor), or in assays for the identification of agonist or antagonists of the receptor protein, and the antibody can be used for other than vaccination or binding the anti-idiotypic antibody, such as to purify the gp75 protein or for immunocytochemical localization of the protein. For these reasons, the  
25 protein of Invention II and vaccine of invention VIII is also distinct from the anti-idiotypic antibody of Invention IV, and the antibodies are additionally distinct from the DNA of invention I.

          The kit of Invention V comprising both the protein and the anti-idiotypic antibody is distinct from the products of Inventions I-IV and VIII because it comprises a distinct

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combination of products not found in the other Inventions, making the use of the kit likewise distinct.

As a result, the DNA of Invention I is unrelated to the methods of Inventions VI, VII and IX-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions do not use the DNA and it does not function in the methods.

Inventions II and VIII are related to VI, VII, IX-XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein may be used for materially different process such as in the production of an antibody and the method of treatment using the protein need not require vaccination with the protein, that is, administration of the protein need not lead to antibody production for therapeutic results.

Inventions III and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody may be used for another materially different process such as purification of gp75 protein or for the production of an anti-idiotypic antibody.

Inventions III and IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions because the method steps do not require the antibody itself, and the method steps of X and XII are only used to detect or interact with the antibody *if* it happens to be present.

Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the anti-idiotypic antibody may be used for another materially different process such as purification of the antibody to gp75 protein.

5       Inventions IV and VI-VII, IX, XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions because the method steps do not require the anti-idiotypic antibody itself, and its use would have a different effect.

10       The kit of Invention V is unrelated to the methods of Inventions VI, VII and IX-XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as used together (*i.e.*, the protein and anti-idiotypic antibody is not required of the methods).

15       Inventions VI and VII are related in that both use and antibody; however, the inventions are distinct because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different modes of operation to accomplish different effects.

20       Inventions VI and VII, which are themselves distinct, and IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as used together, and methods IX-XII do not require use of the antibody (the method steps of X and XII are only used to detect or interact with the antibody *if* it happens to be present) and so have different functions or effects.

25       Inventions IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as used together (treating is distinct from detection), and each method has different modes of operation.

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Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Conclusion*

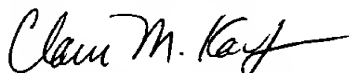
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

September 3, 2002